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EXAMINER

SCHWADRON, R

ART UNIT

PAPER NUMBER

1644

DATE MAILED: 06/22/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.
09/077,214

Applicant(s)

Schmidt et al.

Examiner
Ron Schwadron, Ph.D.

Art Unit
1644



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 2/16/2001 and 4/5/2001
- 2a) ☒ This action is FINAL. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 36-68 is/are pending in the application.
- 4a) Of the above, claim(s) 37, 41, 45-47, 51-68 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 36, 38-40, 42-44, 48-50 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirements.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on _____ is: ☐ approved ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- a) ☐ All b) ☐ Some* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- *See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- 15) ☒ Notice of References Cited (PTO-892) 18) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 19) ☐ Notice of Informal Patent Application (PTO-152)
- 17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____ 20) ☐ Other: _____

1. Claims 36,38-40,42-44,48-50 are under consideration. Claims 36 and 48 have been amended.

RESPONSE TO APPLICANTS ARGUMENTS

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

3. Claims 36,38-40,42-44,48-50 stand rejected under 35 U.S.C. 102(a) as being anticipated by Schmidt et al. for the reasons elaborated in the previous Office Action. Applicants arguments have been considered and deemed not persuasive.

Schmidt et al. teach the claimed invention (see abstract and pages 9761-9763). This rejection can be overcome by supplying a certified English language translation of the foreign priority documents to which the instant application claims priority (assuming said documents disclose the claimed invention).

Regarding the translations of the German priority documents 19543649.0 and 19607044.9 filed 4/5/2001, while said documents include a statement that the translations are a true and exact copy of the original, the name of the translator and the translator's signature are missing (see MPEP 201.15 (Rev. 1, Feb 2000, pages 200-73 to 200-74)).

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person

having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. Claims 36,38-40,42-44,48-50 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nair et al. in view of Fearon et al., Townsend et al., Van Der Bruggen et al. and prior art disclosed in the specification (see page 3).

Nair et al. disclose use of an organic polycation (eg. cationic liposomes) to deliver an MHC class I antigen to tumor cells (see abstract). Nair et al. teach that said method is an efficient means of sensitizing target cells for CTL lysis in the context of MHC class I (see page 242, last sentence). Nair et al. do not disclose human tumor cells treated to express influenza virus peptide in the context of HLA class I. Fearon et al. teach a tumor vaccine wherein tumor cells are transfected with the gene encoding HA (see entire paper). HA is a viral antigen. Townsend et al. teach that influenza HA or NP peptides are recognized by CTL in the context of MHC class I. Van Der Bruggen et al. teach MHC class I restricted tumor antigens and that such antigens can be used to provoke CTL in vivo (see page 15, second paragraph). Van Der Bruggen et al. teach that said peptides can be delivered by vector (to infect APC) or by direct administration of the peptide to APC (see page 15, second paragraph). The art recognizes that tumors express numerous different tumor associated antigens (see prior art disclosed in specification, page 3). It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to have created the claimed invention because Nair et al. disclose use of an organic polycation (eg. cationic liposomes) to deliver an MHC class I antigen to tumor cells, Fearon et al. teach a tumor vaccine wherein tumor cells are transfected with the gene encoding HA while Van Der Bruggen et al. teach MHC class I restricted tumor antigens and that such antigens can be used to provoke CTL in vivo. In view of the fact that the cells disclosed by Nair et al. were treated with intact protein, said cells would have been expected to present multiple different peptides representing different epitopes derived from said molecule. It would also be expected that HA would encode a variety of different epitopes that would bind different HLA molecules found on MHC antigen heterozygous human tumor cells. One of ordinary skill in the art would have been motivated to do the aforementioned because of the demonstration by Fearon et al. of the use of HA transfected tumor cells as a tumor vaccine, while Nair et al. teach that their method is an efficient means of sensitizing target cells for CTL lysis in the context of MHC class I. Regarding the "allogeneic" tumor vaccine limitation, the recitation of an intended use (eg. delivery to an

allogenic host) carries no patentable weight in this product claim.

6. No claim is allowed.

7. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

8. Papers related to this application may be submitted to Group 1600 by facsimile transmission. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). Papers should be faxed to Group 1600 at (703) 308-4242.

9. Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Dr. Ron Schwadron whose telephone number is (703) 308-4680. The examiner can normally be reached Monday through Thursday from 7:30 to 6:00. A message may be left on the examiners voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the Examiner's supervisor, Ms Christina Chan can be reached on (703) 308-3974. Any inquiry of a general nature or relating to the status of this application should be directed to the Group 1600 receptionist whose telephone number is (703) 308-0196.

Serial No. 09077214

Art Unit 1644

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RONALD B. SCHWADRON
PRIMARY EXAMINER
GROUP 1800 (600)

Ron Schwadron, Ph.D.

Primary Examiner

Art Unit 1644

June 21, 2001